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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Swain et al.

Confirmation No.: 9609

Serial No.: 10/647,071

Art Unit: 1639

Filed: August 22, 2003

Examiner: Steele, Amber D.

For: HAPTEN-CARRIER CONJUGATES  
FOR USE IN DRUG-ABUSE THERAPY  
AND METHODS FOR PREPARATION  
OF SAME

Attorney Docket No.: 11662-003-999  
(as amended) formerly 5673-66690-01

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

In accordance with the continuing duty of disclosure provisions of 37 C.F.R. §1.56, there is hereby provided certain information which the Examiner may consider material to the examination of the subject U.S. patent application. It is requested that the Examiner make this information of record if it is deemed material to the examination of the application.

1. Enclosures accompanying this Information Disclosure Statement are:

- 1a. ☒ A list of all patents, publications, applications, or other information submitted for consideration by the office.
- 1b. A legible copy of :
- ☒ Each publication or that portion which caused it to be listed on the PTO-1449;
- ☐ For each cited pending unpublished U.S. application, the application specification including the claims; and any drawing of the application, or portion of the application which caused it to be listed on the PTO-1449 including any claims directed to that portion that have been checked to be unavailable at the USPTO's private PAIR system;
- ☐ An English language copy of search report(s) from a counterpart foreign application or PCT International Search Report;
- ☐ Explanations of relevancy (ATTACHMENT 1(d), hereto) or English language abstracts of the non-English language publications;
- ☐ All other information or portion which caused it to be listed on the PTO-1449.
- 1c. ☒ Pursuant to 37 C.F.R. § 1.98(a)(2)(ii), copies of the cited U.S. patents and U.S. patent application publications are not submitted herewith unless required by the office.
- 1d. ☐ Pursuant to 1287 OG 163, copies of cited pending unpublished applications that are available at the USPTO's private PAIR system are not submitted herewith.

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2. ☐ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(b):
- ☐ Within three months of the filing date of a national application other than a continued prosecution application under §1.53(d);
  - ☐ Within three months of the date of entry of the national stage as set forth in §1.491 in an international application;
  - ☐ Before the mailing of the first Office action on the merits;
  - ☐ Before the mailing of a first Office action after the filing of a request for continued examination under §1.114.
3. ☒ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(c) after the period specified in 37 C.F.R. §1.97(b), but before the mailing date of any of a final action under 37 C.F.R. §1.113, a notice of allowance under 37 C.F.R. §1.311 or an action that otherwise closes prosecution in the application.

*(Check either Item 3a or 3b)*

- 3a. ☐ The Certification Statement in Item 5 below is applicable. Accordingly, no fee is required.
- 3b. ☒ The \$180.00 fee set forth in 37 C.F.R. §1.17(p) in accordance with 37 C.F.R. §1.97(c) is:
- ☐ enclosed.
  - ☒ to be charged to Jones Day Deposit Account No. 50-3013.

*(Item 3b to be checked if any reference known for more than 3 months)*

4. ☐ This Information Disclosure Statement is filed under 37 C.F.R. §1.97(d) after the period specified in 37 C.F.R. §1.97(c), but on or before the date of payment of the issue fee.

The Certification Statement in Item 5 below is applicable.

The \$180.00 fee set forth in 37 C.F.R. §1.17(p) is:

- ☐ enclosed.
- ☐ to be charged to Jones Day Deposit Account No. 50-3013.

5. ☐ Certification Statement (applicable if Item 3a or Item 4 is checked):

*(Check either Item 5a or 5b)*

- 5a. ☐ In accordance with 37 C.F.R. §1.97(e)(1), it is certified that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.
- 5b. ☐ Each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart application, and the communication was not **received** by any individual designated in 37 C.F.R. §1.56(c) more than thirty days prior to the filing of this information disclosure statement.
- 5c. ☐ Pursuant to 37 C.F.R. §1.704(d), each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart application, and the communication was not

received by any individual designated in 37 C.F.R. §1.56(c) more than thirty days prior to the filing of this information disclosure statement.

6. ☐ This application is a continuation application under 37 C.F.R. §1.53(b) or (d).

*(Check appropriate Items 6a, 6b and/or 6c)*

6a. ☐ A Petition to Withdraw from issue under 37 C.F.R. §1.313(b)(5) is concurrently filed herewith.

6b. ☐ Copies of publications listed on Form PTO-1449 from prior application Serial No. , filed on , of which this application claims priority under 35 U.S.C. §120, are not being submitted pursuant to 37 C.F.R. §1.98(d).

6c. ☐ Copies of the publications listed on Form PTO-1449 were not previously cited in prior application Serial No. , filed on , and are provided herewith.

7. ☒ This is a Supplemental Information Disclosure Statement. (Check Item 7a)

7a. ☒ This Supplemental Information Disclosure Statement under 37 C.F.R. §1.97(f) supplements the Information Disclosure Statement filed on October 28, 2005. A bona fide attempt was made to comply with 37 C.F.R. §1.98, but inadvertent omissions were made. These omissions have been corrected herein. Accordingly, additional time is requested so that this Supplemental Information Disclosure Statement can be considered as if properly filed on October 28, 2005.

8. ☐ In accordance with 37 C.F.R. §1.98, a concise explanation of what is presently understood to be the relevance of each non-English language publication is:

*( Check Item 8a, 8b, or 8c)*

8a. ☐ Satisfied because all non-English language publications were cited on the enclosed English language copy of the PCT International Search Report or the search report from a counterpart foreign application indicating the degree of relevance found by the foreign office.

8b. ☐ Set forth in the application.

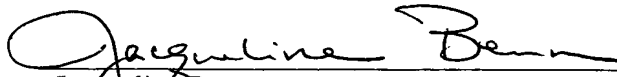
8c. ☐ Enclosed as an attachment hereto.

9. ☒ The Commissioner is authorized to charge any additional fee required or credit any overpayment for this Information Disclosure Statement and/or Petition to Jones Day Deposit Account No. 50-3013.

10. ☒ No admission is made that the information cited in this Statement is, or is considered to be, material to patentability and no representation is made that a search has been made (other than a search report of a foreign counterpart application or PCT International Search Report if submitted herewith). 37 C.F.R. §§1.97(g) and (h).

Respectfully submitted,

Date: February 16, 2007

  
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**LIST OF REFERENCES CITED BY APPLICANT**

(Use several sheets if necessary)

ATTY. DOCKET NO.

11662-003-999

APPLICATION NO.

10/647,071

APPLICANT

Swain *et al.*

FILING DATE

August 22, 2003

ART UNIT

1639

**U.S. PATENT DOCUMENTS**

*Examiner Initials		Document Number	Date mm/dd/yy	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	A01	5,760,184	06/02/98	SWAIN <i>et al.</i>	
	A02	5,773,003	06/30/98	SWAIN <i>et al.</i>	
	A03	5,840,307	11/24/98	SWAIN <i>et al.</i>	
	A04	6,054,127	04/25/00	SWAIN <i>et al.</i>	

**FOREIGN PATENT DOCUMENTS**

*Examiner Initials		Foreign Patent Document Country Code, Number, Kind Code (if known)	Date mm/dd/yy	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T
	B01	EP 0 613 899 A2	9/1994	EP		
	B02	DE 2202441	3/1973	DE		
	B03	DE 2548196	4/1977	DE		
	B04	WO 93/12111	6/1993	PCT		
	B05	WO 94/27576	12/1994	PCT		
	B06	WO 95/07922	3/1995	PCT		
	B07	WO 95/27786	10/1995	PCT		
	B08	WO 96/30049	3/1996	PCT		
	B09	WO 98/14216	4/1998	PCT		

**NON PATENT LITERATURE DOCUMENTS**

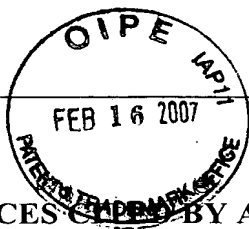
*Examiner Initials		Include name of the author (in CAPITAL LETTERS), (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T
	C01	AMBRE, <i>et al.</i> , "A Kinetic Model of Benzoylcegonine Disposition after Cocaine Administration in Humans," <i>Journal of Analytical Toxicology</i> , Vol. 15, pp. 17-20, January/February 1991.	
	C02	BAGASRA <i>et al.</i> , "A Potential Vaccine for Cocaine Abuse Prophylaxis," <i>Immunopharmacology</i> , 23:173-179, 1992.	
	C03	BECKSTEAD <i>et al.</i> , "Fourier Transform-Infrared (FT-IR) Characterization of Ethyl Acetate Complex of O <sup>6</sup> - Acetylmorphine," <i>J. Forensic Sci.</i> , Vol. 33(1):223-229, 1988.	
	C04	BECKSTEAD <i>et al.</i> , "Fourier Transform-Infrared (FT-IR) Characterization of Ethyl Acetate of O <sup>6</sup> - Acetylmorphine," <i>Chem-Abs.</i> 108:144839, 1998.	
	C05	BERKOWER, "Synthetic T Cell Epitope Peptides Used for Desensitization," <i>Paul-Ehrlich-Institute</i> 1009-1014, 1994.	
	C06	BONESE, <i>et al.</i> , "Changes in Heroin Self-Administration by a Rhesus Monkey after Morphine Immunisation," <i>Nature</i> 252:708-710, 1974.	

NYI-3947562v2

EXAMINER

DATE CONSIDERED

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

**LIST OF REFERENCES CITED BY APPLICANT**

(Use several sheets if necessary)

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**NON PATENT LITERATURE DOCUMENTS**

*Examiner Initials		Include name of the author (in CAPITAL LETTERS), (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T
	C07	CARROLL et al., "Effects of Buprenorphine on Self-Administration of Cocaine and a Nondrug Reinforcer in Rats," <i>Psychopharmacology</i> 106:439-446, 1992.	
	C08	CARROLL et al., "Chemical Approaches to the Treatment of Cocaine Abuse," <i>Pharm. News</i> 1:11-17, 1994.	
	C09	CASTRO et al., "Characterization of Antibodies to Nicotine," <i>Biochemical Archives</i> , 1:173-183, 1985.	
	C10	CASTRO et al., "Nicotine Antibodies: Comparison of Ligand Specificities of Antibodies Produced Against Two Nicotine Conjugates," <i>Chem. Abs.</i> 92:209666, 1980.	
	C11	CASTRO et al., "Characterization of Antibodies to Nicotine," <i>Chem. Abs.</i> 103:213004, 1998.	
	C12	CARRERA et al., "Suppression of Cocaine Induced Locomotion by Immunization with a Novel Cocaine Conjugate," <i>Society of Neuroscience</i> , 754.4 1994 (Abstract).	
	C13	GALLACHER, "A Potential Vaccine for Cocaine Abuse Prophylaxis?" <i>Immunopharm.</i> 27:79-81, 1994.	
	C14	HOLMGREN et al., "Strategies for the Induction of Immune Responses at Mucosal Surfaces Making Use of Cholera Toxin B Subunit as Immunogen, Carrier, and Adjuvant," <i>Am. J. Trop. Med. Hyg.</i> 50(5)Suppl. pp. 42-54, 1994.	
	C15	INABA, "Cocaine: Pharmacokinetics and Biotransformation in Man," <i>SFBS Symposium on Frontiers in Cocaine Research</i> , Quebec, Canada, pp. 1154-1157, 1988.	
	C16	INABA, "Cocaine Pharmacokinetics and Biotransformation in Man," <i>Can. J. Physiol. Pharmacol.</i> , 67:1154-1157, 1989.	
	C17	JATLOW, "Cocaine: Analysis, Pharmacokinetics, and Metabolic Disposition," <i>The Yale Journal of Biology and Medicine</i> , 61:105-113, 1988.	
	C18	JINDAL et al., "Mass Spectrometric Studies of Cocaine Disposition in Animals and Humans Using Stable Isotope-labeled Analogues," <i>J. Pharm. Sciences</i> 78(12):1009-1014, 1989.	
	C19	JONES-WITTERS et al., <i>Drugs and Society - A Biological Perspective</i> , Wadsworth Health Services Division, Wadsworth, Inc. Belmont, CA 90042, pp. 142-147, 1983.	
	C20	KANTAK et al., "Acute and Multiple Injection Effects of Magnesium on Responding Maintained by Cocaine, Extinction from Cocaine, Glucose + Saccharin, and Food," <i>Pharm. Biochem. And Behavior</i> , 41:415-423, 1992.	
	C21	LANDRY et al., "Antibody Catalyzed Degradation of Cocaine," <i>Science</i> , 259:1899-1901, 1993.	
	C22	MANGANARO, "Oral Immunization: Turning Fantasy into Reality," <i>Int. Arch. Immunol.</i> 103:223-233, 1994.	
	C23	SLOS, "Recombinant Cholera Toxin B Subunit in Escherichia Coli: High Level Secretion, Purification, and Characterization," <i>Protein Expression and Purification</i> 5:518-526, 1994.	
	C24	STOK et al., "Conversion of Orally Induced Suppression of the Mucosal Immune Response to Ovalbumin into Stimulation by Conjugating Ovalbumin to Cholera Toxin or its B Subunit," <i>Vaccine</i> , Vol. 12(6):521-526, 1994.	
	C25	VAN VUNAKIS et al., "Specificities of Antibodies to Morphine," <i>The Journal of Pharmacology and Experimental Therapeutics</i> , 180:514-521, 1972.	
	C26	WITKIN, "Pharmacotherapy of Cocaine Abuse: Preclinical Development," <i>Neuroscience and Biobehavioral Reviews</i> , Vol. 18(1):121-142, 1994.	

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